510(k) Summary of Safety and Effectiveness

510k No.: K090650

Submitter:

OCT - 9 2009

- SPSmedical Supply Corp.
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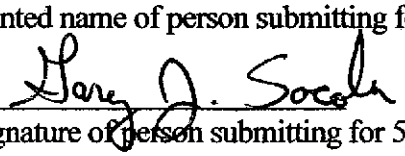
- Establishment FDA Registration No.: 1319130

- Date Summary was Prepared September 21, 2009

- Gary J. Socola
  Printed name of person submitting for 510(k)

- 
  Signature of person submitting for 510(k)

- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators
Classification Name:	Sterilization Process Chemical Indicator
Common Name:	Vaporized Hydrogen Peroxide Chemical Indicators
Device Classification:	General Hospital - Class II, Regulation Number 880.2800
Product Code:	80JOJ
Predicate Device:	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (K030680)

Device Description:

SPSmedical Vaporized Hydrogen Peroxide (H_2O_2) Chemical Indicators are process indicators used to verify exposure to vapor hydrogen peroxide in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro sterilization processes. Indicators will identify if an item has seen H_2O_2 during the sterilization process by changing to a Blue signal color. They provide a visual indication to help distinguish between processed and unprocessed items.

Intended Use:

The SPSmedical Vaporized Hydrogen Peroxide (H_2O_2) Chemical Indicators are process indicators used to verify exposure to the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro sterilization processes. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items.

Statement of Similarity to the Legally Marketed Predicate Device:

- Have the same intended use
- Have the same device design
- Incorporate the same technical characteristics
- Incorporate the same materials
- Have the same endpoint color change
- Have the same shelf life
- Have the same storage conditions
- Packaged using the same materials and processes

Non-Clinical Testing:

Verification and validation tests were performed as a result of a Failure Mode and Effects Analysis (FMEA) assessment.

Various testing, including testing to AAMI/ANSI/ISO 11140:2005 requirements for indicators being run in vaporized hydrogen peroxide sterilization processes was performed. Testing also included simulated use in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro vaporized hydrogen peroxide sterilization processes. Multiple lots of indicators with various levels of shelf life were included in testing.

All lots of SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators gave acceptable results for all test performed.

Conclusion:

For all the foregoing reasons, SPSmedical believes that the SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators are safe and effective when used for routine monitoring of STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro vaporized hydrogen peroxide sterilization processes and can be safely marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary J. Socola
Vice President, Scientific Affairs
SPSmedical Supply Corporation
6789 West Henrietta Road
Rush, New York 14543

OCT - 9 2009

Re: K090650
Trade/Device Name: SPSmedical H_2O_2 Chemical Indicator
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 18, 2009
Received: June 22, 2009

Dear Mr. Socola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K090650

Device Name: SPSmedical H_2O_2 Chemical Indicator

Indications For Use:

The SPSmedical H_2O_2 Chemical Indicators are indicated for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro sterilization processes. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.

Catalog Number	Product Name
GPS-250R	Indicator Strip
GPS-250Y	Indicator Strip
GPL-2000R	Indicator Label
GPL-2000Y	Indicator Label
HT-048	Indicator Tape
HT-036	Indicator Tape
5093	Indicator Card

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090650